REMARKS

Claims 20 - 29 are pending in the application. Claims 1 – 19 and 29 - 31 have been cancelled. Claims 20 and 28 have been amended.

Any cancellation of the claims should in no way be construed as acquiescence to any of the Examiner's rejections and was done solely to expedite the prosecution of the application. Applicant reserves the right to pursue the claims as originally filed in this or a separate application(s).

It is also submitted the amendments made herein may be properly entered at this time, i.e. after final rejection, because the amendments do not raise any new issues or require a new search, and they reduce issues for appeal. In particular, the amendment of claim 20 incorporates subject matter of pending dependent claim 20, which claim has been fully considered. Entry of the amendments at this time is earnestly solicited.

Claim Rejections Withdrawn

The rejection of claim 29 under 35 U.S.C. §112, second paragraph has been withdrawn.

The rejection of claims 20 – 28 under 35 U.S.C. §102 (a) and (b) has been withdrawn.

35 U.S.C. §112, second paragraph

Claims 28 and 29 were rejected under 35 U.S.C. §112, second paragraph, for allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. (Office Action, p.4). The Examiner argues that "the recitation of 'the microarray of claim 20/28, wherein…include one or more genes selected from the group consisting of…GGH…' renders the claims indefinite

because it is unclear whether these claims intends to encompass one or more genes in addition to GGH or including GGH because GGH is already recited in claim 20." Applicants respectfully disagree.

Applicants have amended the claims to provide further clarification of the microarray. Accordingly, Applicants respectfully request that the foregoing rejection be withdrawn.

35 U.S.C. §102

Claims 20 - 29 stand rejected under 35 U.S.C. §102(e) over Erlander et al. (US 2004/002067). (Office Action, p.3). Applicants respectfully traverse the rejection.

Claim 28 depends from claim 20, wherein said genes or polynucleotide fragments or RNA transcripts thereof of said microarray further includes one or more genes selected from the group consisting of C5, GRIA2, RIMS2, ORC4L, CSF2RB, NPAT, NR3C1, P311, PRKAA2, PTK6, APRT, ARF4L, ARHGD1A, ARL7, ATP6F, CDC20, CDC34, CLDN11, COMT, CSTF1, DDX28, DHCR7, ERP70, FEN1, GCN1L1, GNB1, GUK1, HDAC7A, ITPA, JUP, KIAA0469, KRT5, PDAP1, PGAM1, PHB, POLA2, POLD2, POLE3, PYCRI, SIP2-28, SIVA, SURF 1, TADA3L, TK1, TYMSTR, and VATI, or a polynucleotide fragment or RNA transcript thereof. Claim 29 has been cancelled.

To anticipate a claim, each and every element of the claim must be found in a single reference. This is discussed in the Manual of Patent Examining Procedure § 2131:

> A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the . . . claim." Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the

> claim, but this is not an ipsissimis verbis test, i.e., identity of terminology is not required. In re Bond, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990).

The Erlander reference does not teach or suggest all the limitations of the instant claims. In particular, the Erlander reference does not teach or suggest a microarray of genes, or polynucleotide fragments or RNA transcripts for distinguishing a neuroendocrine tumor cell, as instantly claimed, and where the genes or polynucleotide fragments or RNA transcripts includes CPE and GGH, or a polynucleotide fragment or RNA transcript thereof, and further includes one or more genes selected from the group consisting of C5, GRIA2, RIMS2, ORC4L, CSF2RB, NPAT, NR3C1, P311, PRKAA2, PTK6, APRT, ARF4L, ARHGD1A, ARL7, ATP6F, CDC20, CDC34, CLDN11, COMT, CSTF1, DDX28, DHCR7, ERP70, FEN1, GCN1L1, GNB1, GUK1, HDAC7A, ITPA, JUP, KIAA0469, KRT5, PDAP1, PGAM1, PHB, POLA2, POLD2, POLE3, PYCRI, SIP2-28, SIVA, SURF 1, TADA3L, TK1, TYMSTR, and VATI, or a polynucleotide fragment or RNA transcript thereof.

The Examiner argues that Erlander et al. disclose a microarray chip obtained by using 11,435 clones from the IMAGE consortium (and) that the microarray comprises genes including GGH and KIAA0469." (Office Action, p.3).

The Erlander reference is directed to the identification and use of gene expression profiles, or patterns, involved in breast cancer progression. In none of the 850 genes provided in Table 2 does Erlander teach CPE and GGH. In none of the 600 genes provided in Table 3 does Erlander teach CPE and GGH. Nowhere does Erlander teach or suggest that the microarray of genes includes **CPE and GGH**.

Accordingly, Applicants respectfully request that the foregoing rejection be withdrawn.

Claims 20 – 29 stand rejected under 35 U.S.C. §102(e) over Haab et al. (US 2006/0088823). (Office Action, p.4). Applicants respectfully traverse the rejection.

Claim 20 recites a microarray of genes, or polynucleotide fragments or RNA transcripts thereof for distinguishing a neuroendocrine tumor cell, said microarray comprising a solid support having greater than 10 genes, or polynucleotide fragments or RNA transcripts thereof, distinguishably arrayed in spaced apart regions, wherein said microarray comprises a sufficient number of genes, or polynucleotide fragments or RNA transcripts thereof, that are differentially expressed in a small cell lung cancer (SCLC) cell, a large cell neuroendocrine carcinoma (LCNEC) neuroendocrine tumor cell, a typical carcinoid (TC) neuroendocrine tumor cell, or an atypical carcinoid (AC) neuroendocrine tumor cell, relative to a normal cell or a cell belonging to a different neuroendocrine tumor cell type, to permit said microarray to distinguish a neuroendocrine tumor cell, and wherein said genes or polynucleotide fragments or RNA transcripts thereof includes CPE and GGH, or a polynucleotide fragment or RNA transcript thereof.

The Examiner argues that "Haab et al. disclose producing a microarray comprising 21,632 cDNA from a bacterial library…(and) that one of the genes included is GGH." (Office Action, p.4).

The Habb reference is directed to determining the differential expression of a limited set of genes in the prognosis of an aggressive form of clear cell renal cell carcinoma. Haab et al. teach the up- or down-regulation of 129 clones (up) and 168 clones (down), as shown in Tables 2 – 5. In none of the genes provided in Table 2 - 5 does Haab teach CPE and GGH. Nowhere does Haab teach or suggest that the microarray of genes includes **CPE and GGH**.

Applicants respectfully request that the foregoing rejection be withdrawn.

For the reasons provided, Applicant submits that all claims are allowable as written and respectfully requests early favorable action by the Examiner. If the Examiner believes that a telephone conversation with Applicant's attorney/agent would expedite prosecution of this application, the Examiner is cordially invited to call the undersigned attorney of record.

A two month extension of time is requested. It is believed no additional fees are due, however should any fee be due, the Commissioner is authorized to charge such fee to our Deposit Account, No. 04-1105, Reference 63139(47992). Any overpayment should be credited to said Deposit Account.

Respectfully submitted,

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